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| Application No. | : | 10/825,358 |
| Applicants | : | DADD, ET AL. |
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| Title | : | ELECTRODE ARRAY WITH BENDABLE TIP |
| Art Unit | : | 3762 |
| Examiner | : | TO BE ASSIGNED |
| Atty Docket No. | : | COCH-0010-1 |

Commissioner for Patents
P.O. Box 1450
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Sir:

The below-identified communication(s) is (are) submitted in the above-captioned application or proceeding:

☒ Certified Copy of Australian Provisional Application No. 2003901868

☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication, including fees under 37 C.F.R. §§ 1.16 and 1.17 or credit any overpayment to **Deposit Account Number 10-0233-COCH-0010-1.**

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Australian Government

**Patent Office**
**Canberra**

I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901868 for a patent by COCHLEAR LIMITED as filed on 17 April 2003.

CERTIFIED COPY OF
PRIORITY DOCUMENT

WITNESS my hand this
Fourth day of May 2004

LEANNE MYNOTT
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COMMONWEALTH OF AUSTRALIA
AUSTRALIA
PATENT OFFICE

# AUSTRALIA

# Patents Act 1990

**Cochlear Limited**

**PROVISIONAL SPECIFICATION**

*Invention Title:*

*Electrode array with bendable tip*

The invention is described in the following statement:

"Electrode Array with Bendable Tip"

Technical Field

The present invention relates to electrode arrays for use with prostheses, such as hearing prostheses in which an electrode array is implanted in a cochlea of a recipient.

Background of the Invention

Electrode array assemblies, such as cochlear implant electrode array assemblies, generally consist of a plurality of electrode elements which are adapted to apply electrical stimulation to surrounding tissue to stimulate the surrounding nerves. In cochlear implant applications, the electrode array assembly is implanted within the cochlea of a recipient and applies stimulation to the auditory nerves via a series of electrode elements, in accordance with a set stimulation pattern, controlled by an implanted stimulator unit.

The implanted stimulator unit typically applies the stimulation in a manner which is representative of a detected acoustic signal, such that the stimulation pattern applied by the electrode array assembly stimulates the auditory nerves and elicits a sensation that closely resembles the natural sensation of the detected acoustic signal.

In this regard, it is important that when implanting electrode arrays in sensitive regions of the body, such as the cochlea, that the electrode array be designed in such a manner as to be flexible enough to reduce damage to the sensitive structures of the surrounding tissue, and yet be rigid enough to ensure that the general shape and form of the electrode array is maintained during the insertion procedure such that the electrode array can perform as intended.

In electrode arrays of the type used for implantation in the cochlea, it has been found that the tip of the array plays an important role during the insertion procedure. In this regard, there have been attempts to design the tip of the electrode array in a manner that reduces the possibility of the tip of the electrode puncturing or abrading the sensitive tissues of the cochlea and causing damage to the nerve structures which the implant is attempting to stimulate.

One such early attempt is described in Australian Patent No. 582264 to Clark et al. This patent discloses the provision of tip or distal end of the electrode array being provided with at least one discontinuity that increases the flexibility of the tip. The tip is generally an extension of the existing electrode array and is made from the same material, but is extending beyond the most distal electrode element.

One problem with such a design is that the tips were typically relatively too flexible such that during the insertion process the tip would catch on the wall of the cochlea and cause the array to bend back on itself, thereby potentially causing more damage to the cochlea than would ordinarily be the case should the flexible tip not be provided. Such a situation can also result in an implant being incorrectly positioned remote from the auditory nerve potentially reducing the effectiveness of the array in capturing and stimulating the appropriate nerves. Further, such a situation where the array folds upon itself can cause unwanted interaction or shorting between electrode elements that may be touching, thereby reducing the number of electrodes that may be operational for stimulation.

Other applications have also considered providing an extended flexible tip of a lead or electrode array to aid in insertion, such as that described in EP 0919254 to Bakels et al. However, as mentioned above, such tips have all been designed with flexibility in mind rather than stability of the tip, hence all suffer from similar problems as identified above.

The present invention therefore aims to provide a solution to the abovementioned problems of the prior art and provide a tip for an electrode array that is designed to provide stability and flexibility to the electrode array and to assist in guiding the electrode array during insertion thereof.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member having a body having a first end, the elongate member having at least one electrode mounted thereon to apply a preselected tissue stimulation; and

a resiliently flexible tip member extending forwardly from the first end of the body;

wherein the tip member has a frusto-conical portion and decreases in diameter over the length of the frusto-conical portion away from the first end of the body towards a distal end of the tip member.

In a preferred embodiment, the tip member is also cylindrical in form for a portion of its length. In another embodiment, the tip member is also preferably part-spherical for a portion of its length.

In a preferred embodiment, the cylindrical portion comprises a first portion of the tip member extending along the tip member for a distance from the proximal end thereof. The cylindrical portion can be exactly or about 0.4mm in length. The diameter of the cylindrical portion is preferably exactly or about 0.45mm.

In a further preferred embodiment, the frusto-conical portion extends forwardly from the cylindrical portion. The frusto-conical portion can have a length of about 0.76mm. Over this length, the diameter of the frusto-conical portion decreases from or about 0.45mm to exactly or about 0.2mm. The angle between notional diametrically opposed sides of the frusto-conical portion is preferably exactly or about 18.9°.

In another preferred embodiment, the part-spherical portion extends forwardly from the frusto-conical portion to form a rounded end to the tip member. The length of

the part-spherical portion is preferably about 0.04mm. Over this length, the diameter of the tip member decreases from or about 0.2mm to the most distal end.

The cylindrical portion preferably has a lumen therein that extends for some or all of its length. In one embodiment, the lumen can be about 0.3mm. The lumen can have a diameter of about 0.125mm. The lumen can be adapted to receive the distal end of a stiffening member, such as a stylet.

According to a second aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member having a body having a first end, the elongate member having at least one electrode mounted thereon to apply a preselected tissue stimulation; and

a resiliently flexible tip member having a proximal end and a distal end and extending forwardly from the first end of the body;

wherein the tip member has a length of about 1.2mm and has a frusto-conical portion over which the tip member decreases in diameter away from the proximal end of the tip member towards its distal end, the diameter of the frusto-conical portion decreasing from about 0.45mm to about 0.2mm over its length.

In a preferred embodiment of the second aspect, the tip member is cylindrical in form for a portion of its length. In another embodiment, the tip member is also preferably part-spherical for a portion of its length.

In a preferred embodiment of the second aspect, the cylindrical portion comprises a first portion of the tip member extending along the tip member for a distance from the proximal end thereof. The cylindrical portion can be exactly or about 0.4mm in length. The diameter of the cylindrical portion is preferably exactly or about 0.45mm.

In a further preferred embodiment of the second aspect, the frusto-conical portion extends forwardly from the cylindrical portion. The frusto-conical portion can have a length of about 0.76mm. As described, over this length, the diameter of the frusto-conical portion decreases from 0.45mm to 0.2mm. The angle between notional diametrically opposed sides of the frusto-conical portion is preferably exactly or about 18.9°.

In another preferred embodiment of the second aspect, the part-spherical portion extends forwardly from the frusto-conical portion to form a rounded end to the tip member. The length of the part-spherical portion is preferably about 0.04mm. Over this length, the diameter of the tip member decreases from or about 0.2mm to the most distal end.

The cylindrical portion preferably has a lumen therein that extends for some or all of its length. In one embodiment, the lumen can be about 0.3mm. The lumen can have a diameter of about 0.125mm. The lumen can be adapted to receive the distal end of a stiffening member, such as a stylet.

The tip member of both aspects is designed that when it is subject to a bending force, the moment of that force is evenly distributed along the tip member and the bending stresses on the tip are constant throughout its length. This even distribution is adapted to prevent foldover of the tip member when the tip member is subject to a bending force, such as may occur during insertion of the tip member into a recipient of the device.

In one embodiment of both aspects, the tissue-stimulating device can be a cochlear implant, with the elongate member comprising a carrier member for a plurality of electrodes. The tip member in this embodiment can be constructed to assist in the guiding of the elongate member into the cochlea, particularly the scala tympani of the cochlea.

In a further embodiment, the elongate member can have a first configuration selected to allow said member to be inserted into an implantee's body and at least a second configuration wherein said elongate member is adapted to apply the preselected tissue stimulation. In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

In a still further embodiment, the elongate member can have a receiving portion. The device can still further include a removable stiffening member positionable within the receiving portion of the elongate member and having a configuration selected for

biassing said elongate member into said first configuration. The stiffening member is preferably relatively stiffer than said elongate member.

The elongate member can be formed from a resiliently flexible material.

In a further embodiment, the tip member is resiliently flexible. In one embodiment, the tip member can be formed of a material having the substantially the same or the same resilient flexibility as the material used to form the body of the elongate member that encapsulates the electrode element(s) and wires.. In a further embodiment, the tip member can be formed of a material having a relatively lesser stiffness than a portion of the body of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member.

The tip member is preferably formed separately to the body of the elongate member and then is mountable to the first end of the elongate member. For example, the tip member can be adhered to the first end of the body of the elongate member or be moulded thereto in a secondary moulding step. The tip member can be formed from a silicone material. In another embodiment, the tip member can be formed of an elastomeric material, such as polyurethane.

In both aspects, the body of the elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment of both aspects, the body of the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone. In another embodiment, the body can be formed from a suitable elastomeric material, such as a polyurethane.

In one embodiment of both aspects, the stiffening member is formed of a bioresorbable material which dissolves on exposure to a fluid. The stiffening member can dissolve on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment of both aspects, the bioresorbable material of the stiffening member is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment of both aspects, the stiffening member can comprise a stiffening element formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic stylet extending through the receiving portion of the body of the elongate member. In one embodiment, the wire can be formed from a biocompatible metal or metallic alloy. In a preferred embodiment, the metal stylet can be formed from platinum.

In a still further embodiment of both aspects, the stiffening element can be formed from a shape memory or heat sensitive material. For example, the stiffening element can be formed from a bimetallic element (such as nickel/titanium) and shaped to take a straight or substantially straight configuration at room temperature but bends into another shape once it is exposed to body temperature.

In one embodiment of both aspects, the receiving portion can comprise a lumen extending at least into, and more preferably through, the body of the elongate member. The lumen for the stylet can be cylindrical and also can have an opening formed therein distal the tip member. In the case of a metal stylet, the stylet can extend out of the opening allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device.

The construction of the electrode assembly of the present invention is adapted to minimise the likelihood of trauma to the cochlea caused by electrode assembly insertion. The construction of the tip member is envisaged by the present inventors to assist in guiding the electrode down the lumen of the scala tympani of the cochlea. It is also envisaged that it will minimise the potential for the tip of the electrode to perforate the basilar membrane of the cochlea or damage other sensitive structures in the cochlea.

Still further, the tip member is particularly useful for those elongate members inserted in the cochlea using an Advance-Off-Stylet (AOS) mode of implantation. In this mode, the elongate member while mounted on a stylet is inserted through a cochleostomy until the tip member is positioned just short of the basal turn of the cochlea. Once it has reached this position, the elongate member can be advanced off the stylet and further into the scala tympani. As the elongate member is advanced off the stylet, it is also free to begin to adopt its preferential spiral curvature. The construction of the tip member preferably prevents foldover of the tip member as it is moved off the stylet. The length is, however, also sufficiently short to ensure that the tip member does not damage the walls of the scala tympani once the elongate member has reached its desired final insertion position well in to the cochlea.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1a is a force diagram of a prior art tip used in electrode arrays;

Fig. 1b is a force diagram of another prior art tip used in electrode arrays;

Fig. 2 is a side view of the tip in accordance with the present invention;

Fig. 3 is an end view of the tip of Fig. 2 connected to a conventional electrode array carrier member; and

Fig. 4 is a cross sectional view of the tip of Fig. 2 along A-A.

Best Mode for Carrying out the Invention

Figures 1a and 1b represent force diagrams of typical tips of known prior art electrode array carrier members. It is possible from a review of these two diagrams to identify the problems with such prior art tips.

Figure 1a represents a tip design 10 where the tip 11 is essentially an extension of the electrode array carrier member 12. The most distal electrode of the array is

depicted as 13 in this diagram. The tip 11 has a relatively narrow diameter neck section 14 which is designed to provide increased flexibility to the tip 11. As is shown, during insertion a force (represented by arrow F) is applied to the tip 11 when the array comes into contact with the wall of the cochlea during insertion. Due to this force F, the tip 11 will flex about the neck section 14 (shown by the dotted line) causing the distal tip, or bulbous portion, to undergo excessive deflection, greatly increasing the possibility of the tip 11 folding over upon itself during insertion.

Similarly, Figure 1b represents a tip 20 having a constant cross-sectional diameter along its length, with the tip 20 again essentially being an extension of the carrier member 12 for the electrode array beyond the position of the most distal electrode. As is shown, when the force (represented by arrow F) is applied to the distal end of the tip 20, the tip 20 will flex about a location where the tip joins that portion of the carrier member bearing the electrodes. This design increases flexibility due to the long arm of the impact force and as such there is an increased risk of such a tip design causing array foldover and potential damage to the sensitive structures of the cochlea.

Figure 2 represents one embodiment of the tip design of the present invention. As is shown, the general appearance of the tip design 30 is at least partially frusto-conically tapering in form, with the diameter of the tip decreasing with a relatively gentle taper.

In the depicted embodiment, the tip 30 is constructed separately from the carrier member 31 carrying the electrode array. This allows the tip 30 to be constructed in a manner that ensures the parameters of the tip 30 are appropriately controlled to ensure that the tip fulfils its designed purpose.

The depicted tip 30 is to be understood as having been made from a flexible material such as silicone, which is consistent with the material that forms the body of the electrode array 31. Other suitable materials can be envisaged.

The dimensions and shape of the depicted tip 30 are important and have been chosen specifically, based on the flexibility requirements for a smooth insertion of the electrode array and effective avoidance of tip foldover.

The tip design essentially provides a smooth transition of flexibility from the relatively stiff portion of the carrier member 31 containing the electrode elements and wires to the more flexible distal end 32 of the tip 30.

As depicted, the tip 30 has a frusto-conical portion 33, a cylindrical portion 34 and a distal end formed from a part-spherical portion 35.

The cylindrical portion 34 comprises a first portion of the tip member 30 extending along the tip member for a distance from the proximal end 36 thereof. The cylindrical portion 34 can be exactly or about 0.4mm in length. The diameter of the cylindrical portion 34 is preferably exactly or about 0.45mm for all or at least some of its length.

The frusto-conical portion 33 extends forwardly from the cylindrical portion 34. The depicted frusto-conical portion 33 has a length of about 0.76mm. Over this length, the diameter of the frusto-conical portion 33 decreases from or about 0.45mm to exactly or about 0.2mm. The angle between notional diametrically opposed sides of the frusto-conical portion 33 is exactly or about 18.9°.

The part-spherical portion 35 extends forwardly from the frusto-conical portion 33 to form a rounded end 32 to the tip member 30. The length of the part-spherical portion 35 is preferably about 0.04mm. Over this length, the diameter of the tip member decreases from or about 0.2mm to the most distal end.

As depicted in Fig. 4, the cylindrical portion 34 has a central lumen 37 therein that extends from the proximal end 36 for a length into the tip member 30. In the depicted embodiment, the length of the lumen 37 is about 0.3mm and it has a diameter of about 0.125mm. The lumen 37 can be adapted to receive the distal end of a stiffening member, such as a stylet, as is described in more detail below.

As indicated above, the design of the tip 30 is essentially based upon establishing the dimensions of three main parameters:

D1 - the diameter of that portion of the tip 30 that is connected to the electrode array carrier member 31;

D2 - the diameter of the distal end of the frusto-conical portion 33 of the tip 30; and

L - the length of the tip 30.

As depicted, the diameter D1 of the tip 30 at its proximal end 36 that is connected to the end of the electrode array 31 is preferably exactly or about 0.45mm. This diameter allows the tip 30 to be easily fitted onto the end of a conventional electrode array, such as the Contour electrode array manufactured by Cochlear Limited of Lane Cove, New South Wales, Australia. Figure 3 depicts the relative dimensions of the diameter of the proximal end of the tip 30 to that of the carrier member 31.

The diameter D2 of the distal end of the frusto-conical portion 33 of the tip 30 is preferably exactly or about 0.2mm. This diameter has been determined by the present applicant based upon studies and experimental measurements of human cochleae and the sizes of the diameter of the outer wall of the cochlea as a dimension most likely to minimise the chance of the tip 30 penetrating the outer wall.

The length L of the tip 30 is preferably exactly or about 1.2mm. Again, this dimension has been determined by the present applicant as being suitable for ensuring the tip 30 fits within the appropriate region inside the cochlea for a range of initial electrode array insertion depths. It has been found that such a length of the tip 30 minimises the likelihood of, and more preferably avoids, tip foldover for typical forces associated with electrode array insertion.

Having determined the important parameters of the tip of the present invention, namely D1, D2 and L - the shape of the tip has been determined in accordance with the design that provides maximum flexibility whilst providing smooth mechanical interaction between the tip and the cochlea thereby providing the smoothest insertion procedure.

The preferred shape of the tip has been determined taking into consideration the mechanical design requirements of the tip. It has been recognised by the present applicant that the best mechanical beam springs are constant-strength cantilever beams where bending stresses throughout the beam are equal to those at the fixed end (that is, the junction of the tip with the electrode array).

In this regard, the general stress formula for such a cantilever beam (assuming a rectangular cross-section) is:

$$\sigma = 6FL/(bh^2)$$

where $\sigma$ - stress;
F - deflection/impact force; and
L,b,h - beam length and fixed end width and height.

As the tip of the present invention is preferably to be attached to a substantially tubular electrode array, the preferred cross-section of the tip is circular, so that there is maximum alignment between the electrode array and the tip when the tip is attached to the array during production. In this regard, for a circular beam the constant stress formula can be written as:

$$\sigma = k(\text{const.}) \times ((F.x)/D^3)$$

where x - arm of force F (see Figure 4); and
D - diameter.

Therefore, for a given impact/deflection force F (constant), in order to achieve uniform strength the following formula can be found:

$$X/D^3 = k' \text{ (const.)}$$

Therefore the formula for D as a function of x is:

$$D = k''(\text{const.}) \times \text{cube root } (x)$$

Given the abovementioned established parameters of the tip, namely D1 D2 and L, the following equations can be determined:

$$0.2 = k''(\text{const}) \times \text{cube root}(x)$$
$$0.45 = k''(\text{const}) \times \text{cuberoot } (x = 1.2)$$

As a result, in order to control the distribution of the force over the length of the tip, the shape of the tip 30 of the present invention can be approximated to the partially frusto-conical tapered shape as depicted in Figure 2.

As mentioned, it is preferred that the tip 30 be constructed separately from the carrier member 31 of the electrode array. In this regard, the tip 30 can be constructed out of a similar material to the body of the electrode array carrier such as silicone. To aid in fixing the tip to the electrode array during production, the lumen 37 can be used to fit over a production stylet positioned within the carrier member 31 of the electrode array during its manufacture. Such a production stylet is typically placed in a mould, along with the electrodes, and a suitable quantity of silicone is then poured into the mould around the stylet and electrodes to form the carrier member 31. In the present embodiment, the distal end of the production stylet would preferably extend a relatively short distance out of the distal end of the moulded carrier member and act as a support for the lumen 37 of the tip member 30 when it is subsequently securely affixed to the distal end of the carrier member 31. The production stylet and a method of manufacturing the carrier member of the electrode array is described in more detail in the present Applicant's US Patent No 6421569.

The present invention therefore provides a specifically designed tip of an electrode array that is shaped and dimensioned in a manner to optimise the flexibility of the array such that the tip will not undergo fold-over during insertion when exposed to usual insertion forces. This invention is a significant improvement over prior art attempts at providing such a flexible tip as it overcomes the problem of the tip being too flexible at a critical section and becoming too flexible to enable smooth insertion of the array.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this seventeenth day of April 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

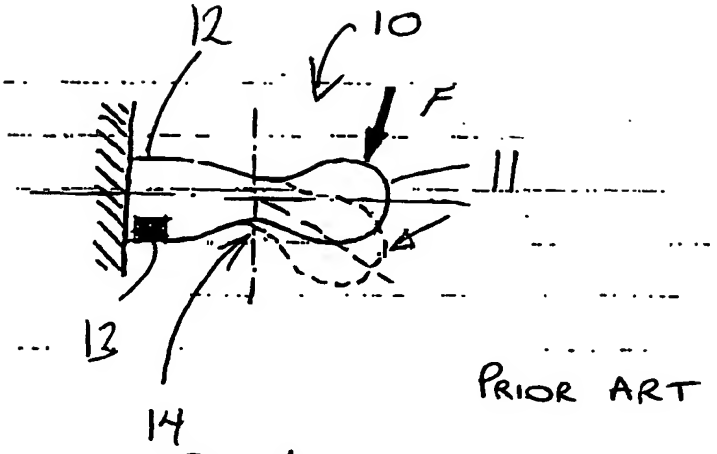


Fig 1a

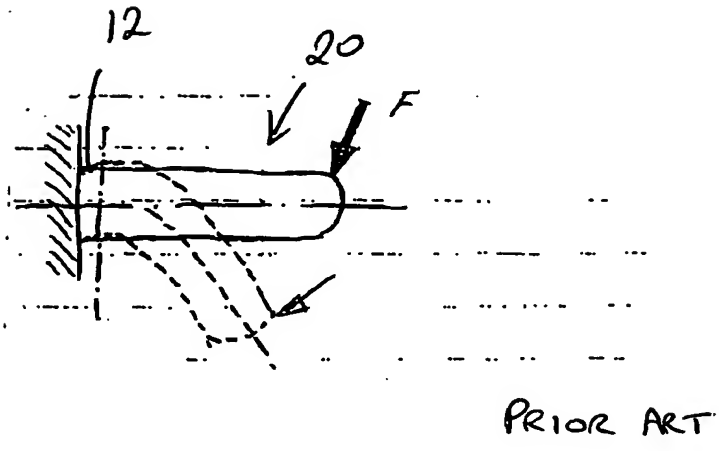


Fig 1b

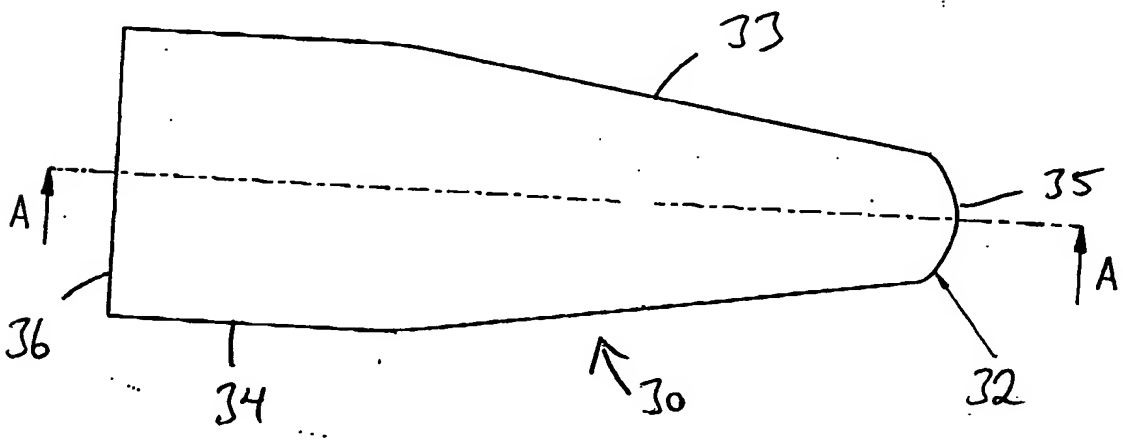


Fig 2

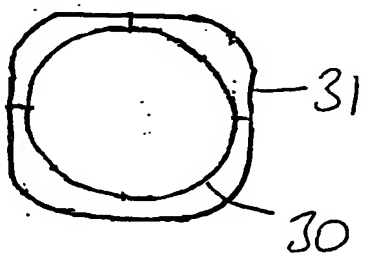


Fig 3

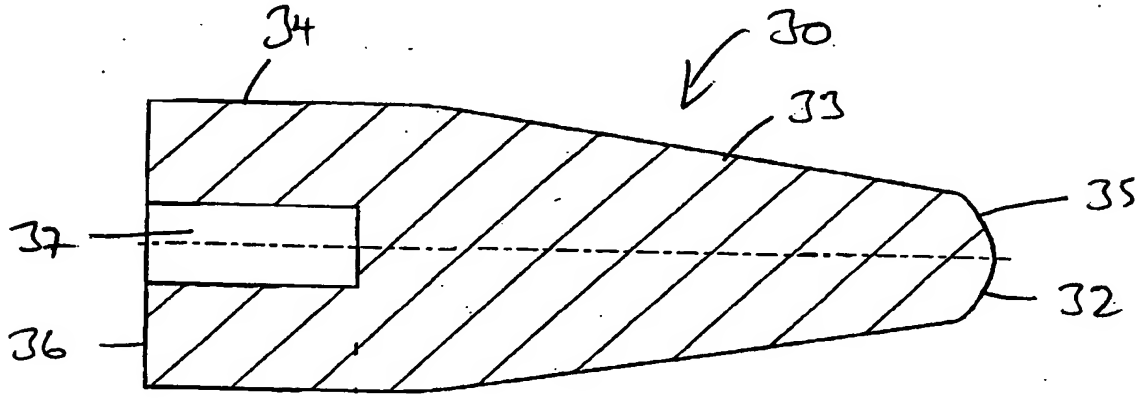


Fig. 4.